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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/822,496	04/12/2004	Larry F. Lemanski	6818-70	3665

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EXAMINER	
TSAY, MARSHA M	
ART UNIT	**PAPER NUMBER**
1653	

DATE MAILED: 07/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/822,496	LEMANSKI ET AL.	
	Examiner	Art Unit	
	Marsha M. Tsay	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 May 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) *15-24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *11/18/04; 05/02/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

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DETAILED ACTION

Claims 15-24 are withdrawn. Claims 1-14 are pending and currently under examination.

Priority date is April 10, 2003.

Newly submitted claim 1, drawn to SEQ ID NO: 4, directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the polynucleotide as depicted by SEQ ID NO: 4 was not elected and searched in the first office action.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 1, drawn to SEQ ID NO: 4, is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Withdrawal of Objections and Rejections

The rejection of claims 1-14 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn.

The rejection of claims 1-3, 7, 10, 14 under 35 U.S.C. 112, second paragraph as being indefinite is withdrawn. However, new issues under 35 U.S.C., second paragraph, are included in this action and explained below.

The rejection of claims 1-3, 7-9, 11, 13 under 35 U.S.C. 102(b) as being anticipated by Lemanski et al. (1996 Biochem. Biophys. Res. Comm. 229: 974-981) is withdrawn.

Maintenance of Objections and Rejections

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 10 is rejected again under 35 U.S.C. 102(b) as being anticipated by Lemanski et al. (1996 Biochem. Biophys. Res. Comm. 229: 974-981). Lemanski et al. teach the preparation of synthetic RNA from the cDNA of clone #4, where the RNA was found to be active in rescuing mutant hearts as determined by their initiating contractions and forming organized myofibrils containing tropomyosin (p. 976, results; claim 10).

New Objections and Rejections

The disclosure, specifically the brief description of drawings, is objected to because of the following informalities: Figure 3 has sequences that need SEQ ID NOs. in the description; Figure 5 does not match the description provided for the drawing because the figure has two structures labeled as A and B, however, the

description recites structures that are placed in a left and right orientation; Figure 8 lacks SEQ ID NOs in the description.

Appropriate correction is required.

Claims 1, 7, 10, 13 are objected to because of the following informalities: the notation for the SEQ ID numbers should be written such that "SEQ ID NO.: 1" is "SEQ ID NO: 1"; in claim 10, the conjunction "and" should be inserted between "167" and "up to 620 nucleotides in length." Appropriate correction is required.

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-14 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

The instant claims are drawn to a MIR molecule. The instant invention discloses MIR is a myofibrillogenesis-inducing RNA molecule that has the functional activity of binding or interacting with MIR-binding proteins to induce myofibrillogenesis and promote normal cardiac muscle phenotype. Applicants have not yet named the MIR-binding proteins but have categorized the instant proteins to have MWs of ~11-13 kDA and ~28-30 kDa. In addition, the instant specification also discloses that any protein that specifically binds a MIR molecule can be considered to be a MIR-binding protein. The instant

specification defines MIR molecules are ribonucleic acids that are complementary to the DNA that transcribes them (p. 10, line 26). The specification further disclose the MIR molecules have bioactive properties such as 1) inducing heart beating and myofibrillogenesis and 2) binding to specific MIR-binding proteins (p. 11, line 1-2). While the instant invention has established the binding of MIR to MIR-binding proteins, it has not established a specific and substantial utility for the MIR molecules. The induction of heart beating and myofibrillogenesis is activated or coordinated by protein activity, in this instance, the MIR-binding proteins. However, even these MIR-binding proteins are not well known since Applicants have yet to identify or name them.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-14 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-2, 7, 10, 13 are drawn to a purified nucleic acid comprising a nucleotide sequence that encodes a MIR molecule. As disclosed in the instant invention, a MIR molecule is a RNA molecule. It is known in the art, that the term "encodes" is used in the sense that DNA encodes protein. Since the instant claim is drawn to RNA and not protein, it is suggested that another term be used to describe the transcription of the DNA to RNA. A possible suggestion is: A purified nucleic acid comprising a nucleotide sequence that is transcribed into a myofibrillogenesis-inducing RNA (MIR) molecule. Additionally, RNA does not have "functional activity" per se, so it is unclear what the activity of RNA is.

Claims 6, 8-9, 11-12, 14 are included in this rejection because they are dependent on claim 1.

Claim 3 is drawn to a purified nucleic acid whose complement hybridizes under low, moderate or high stringent hybridization conditions to the nucleotide sequence of at least SEQ ID NO: 2 and SEQ ID NO: 3. The claim is considered indefinite because it does not further limit claim 1, but broadens it.

Claim 4 is drawn to a purified nucleic acid sequence that comprises SEQ ID NO: 1 and is greater than 166 nucleotides in length. The claim is indefinite because it does not disclose how many additional nucleotides can be added or which nucleotides can be added, such that the functional activity of the MIR molecule will not be disrupted.

Claim 5 is drawn to a purified nucleic acid sequence that shares at least 75% sequence identity with SEQ ID NO: 5. The sequence identity of the polynucleotide can be greater or equal to 75%. The claim is considered indefinite because it does not further limit claim 1, but rather broadens it.

Claim 7 is drawn to a purified nucleic acid wherein a portion of the nucleotide sequence that encodes a MIR molecule comprises a first polynucleotide sequence, SEQ ID NO: 5, that shares sequence identity with a second polynucleotide. The claim is indefinite because it is unclear what degree or percentage of identity the first polynucleotide shares with the second polynucleotide. It is also unclear why the sequence identity of the first polynucleotide sequence is drawn to a second polynucleotide sequence within the 5^1 untranslated region of a nucleic acid. It is unclear what significance can be attributed to an untranslated region of a polynucleotide sequence since it is not translated.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 13-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lemanski et al. (1996 Biochem. Biophys. Res. Comm. 229: 974-981). Lemanski et al. teach the construction of a cDNA library in a pcDNAII vector with

T7 and Sp6 polymerase promoters. Synthetic RNA was prepared *in vitro* by T7 RNA polymerase and found to be active in rescuing mutant hearts as determined by their initiating contractions and forming organized myofibrils containing tropomyosin. Lemanski et al. teach an active and unique clone (Cl#4), depicted in Fig. 1, that is transcribed into a MIR molecule having at least one functional activity of a native MIR molecule. Lemanski et al. do not teach a nucleic acid as identified by SEQ ID NO: 5.

It would have been obvious to a person having ordinary skill in the art to construct a vector, such as pcDNAII, comprising a purified nucleic acid that transcribes a MIR molecule having at least one functional activity of a native MIR molecule because Lemanski et al. teach the construction of a vector comprising a polynucleotide sequence that is used to prepare a homologous myofibrillogenesis-inducing RNA (MIR) molecule and further encodes a MIR-binding protein.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marsha M. Tsay whose telephone number is 571-272-2938. The examiner can normally be reached on M-F, 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Jon Weber can be reached on 571-272-0925. The fax

phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

July 25, 2005

JON WEBER
SUPERVISORY PATENT EXAMINER